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Title: Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: a pilot randomized clinical trial

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Abstract:

Objective: To examine the effectiveness of group mindfulness-based intervention (MBI) in patients diagnosed with severe mental illness. The primary outcome was health-related psychological quality of life. Secondary measures were environmental, social and physical health related quality of life, frequency and intensity of psychotic symptoms and daily-life mindfulness.

Method: Forty-four patients from a public community rehabilitation centre for people with severe mental illness were recruited, and randomly allocated to Integrated

Rehabilitation Treatment (IRT) or IRT plus MBI. Measures included PANSS interview, WHOQOL-BREF, and Mindfulness Attention Awareness Scale. MBI comprised 26 one-hour weekly sessions. Intention–to-treat analysis was used.
Results: One patient did not complete IRT+MBI and two did not complete IRT. At baseline there were no statistical group differences in demographic characteristics or primary and secondary outcomes. At post-treatment interaction between treatment and time in health-related psychological quality of life was statistically significant, and simple effects analysis showed significant differences for between and within subjects factor in favour of MBI. Interaction was also significant in PANSS Negative symptoms, simple effects showed a statistical trend in within subjects factor. Time factor was significant in environmental and physical quality of life.
Conclusions: Data suggest mindfulness added to IRT may enhance psychological quality of life in people with severe mental illness from a public community centre. Results also suggest that mindfulness may impact frequency and intensity of negative symptoms.

Keywords: mindfulness, negative symptoms, severe mental illness, quality of life, schizophrenia.

1. Introduction

Severe mental illness (SMI) affects 5.8% of the population in developed countries (Kessler et al., 2005). According to Parabiaghi et al. (2006) people with SMI mainly suffer persistent psychotic symptoms, chronic course and significant impairment of social functioning, thus a wide range of disorders can be included within this category (i.e. schizophrenia, bipolar disorder etc.). Furthermore, the American Psychological Association (APA) states that SMI involves impairment in psychological functioning of such severity that a person's ability to perform routine demands of daily life is significantly compromised, and its consequences for a person's social functioning are severe and persistent (APA, 2009). All definitions of SMI (e.g. Kessler et al., 2005) have a common consequence for the person who suffers it: high psychological distress and poor quality of life (QoL).

Treatment in SMI patients mainly consists in reducing or controlling core symptoms, so pharmacotherapy (i.e. antipsychotics or mood stabilizers) is accepted as the base of the treatment plan (Gardner and Bostwick, 2012; Malhi et al., 2012). Nevertheless pharmacotherapy has several limitations: unwanted side effects (i.e. weight gain, abnormal movements etc.), low impact on negative symptoms, positive symptoms persists in spite of treatment in around a third of cases, and a major problem of non-adherence to treatment, relapse and rehospitalisation. To address these issues, pharmacotherapy has been combined with psychosocial rehabilitation programmes drawing from psychotherapy, family intervention, and training in social skills and illness management (APA, 2009). In recent years, there is increasing interest in how such programmes might best improve QoL of people with SMI. In this regard, mindfulness would be a suitable addition to psychosocial rehabilitation due to its effectiveness in improving QoL in disorders characterized by treatment-resistant symptoms (Lauche et al., 2013; Reiner et al., 2013; Zainal et al., 2013).

Mindfulness has been operationalized as the self-regulation of attention to focus on the present-moment experience with openness and acceptance (Bishop et al., 2004). Thus mindfulness-based interventions (MBI) are assumed to decrease distress through a set of interrelated processes facilitating a mode of present-centred awareness wherein the individual relates to experience with acceptance instead of avoidance or control (Williams, 2010). Outcome research on mindfulness for psychosis has been slow to develop, perhaps because of concerns based on isolated case reports of traditional meditation sometimes being either too difficult or even harmful to this client group (Chadwick, 2014). For example, Deatherage and Lethbridge (1975) argue that traditional meditation may require too much motivation and “rationality” for some persons with psychosis, at least in the early stages of the therapy. Again, Yorston (2001) reports how traditional meditation triggered onset of mania in two cases. However, contemporary mindfulness for psychosis has been developed specifically for people with psychotic symptoms, and has shown promise and no negative effects (Chadwick, 2014). Three pilot studies offered preliminary evidence that group MBI for people with psychosis has beneficial effects and increases mindfulness skills (Chadwick et al., 2009; Chadwick et al., 2005; Langer et al., 2012). Furthermore, a qualitative study of 16 people who completed mindfulness for psychosis groups (Abba et al., 2008) described a psychological process whereby patients began to reclaim power previously invested in distressing voices and paranoid beliefs, and to feel greater self-control and self-acceptance.

A recent meta-analysis estimates that interventions that include mindfulness have a medium effect on QoL in patients with psychotic symptoms (Khoury et al., 2013), though analysis does not separate interventions that are primarily mindfulness-based from those where mindfulness practice is part of a broader therapy. The present study uses a randomised controlled trial to compare the effect of group MBI plus rehabilitation versus rehabilitation alone on health-related psychological quality of life in 44 patients with SMI attending a public community rehabilitation centre. Secondary measures assessed if mindfulness-based intervention affects other dimensions of health-related quality of life (environmental and physical), psychotic symptomatology, and mindfulness skills.

2. Materials and Methods

2.1. Design

A single centre, randomized clinical trial with pre and post-treatment measures was designed. There were two treatment arms: Integrated Rehabilitation Treatment (IRT) and IRT enhanced with group MBI.

The study complied with the Declaration of Helsinki and ethical approval was granted by the Research Ethics Committee of the University of Balearic Islands. Intention-to-treat analysis was used to avoid overestimation of the efficacy resulting from removal of non-compliers. Multiple stochastic imputation was selected to deal with missing data - an appropriate and robust method (Baraldi & Ender, 2009), and recommended to deal with data missing at random (Fielding, Fayers & Ramsey, 2012). This pilot trial follows the JARS Group recommendations (Cooper, 2008) for randomized clinical trials reporting standards.

2.2. Study sample

51 patients from a public community rehabilitation centre for people with SMI were asked to participate. Inclusion criteria were 1) age between 18-65, 2) clinical record of schizophrenia, schizoaffective or bipolar disorder, 3) being in a stable post-acute phase of illness defined as having experienced no changes in psychiatric medication or hospitalization in the last month, 4) previous history of psychotic symptoms, 5) no prior experience of mindfulness or yoga-based interventions, 6) be able to understand and read Spanish language, and 7) gave written informed consent. Exclusion criteria were 1) significant cognitive impairment, 2) inability to attend mindfulness sessions, 3) posed a risk of violence to the researchers. No payment was made for participation in the study. Recruitment took place between December 2012 and February 2013 for first group and between July 2013 and August 2013 for second group.

2.3. Measures

The primary outcome measure was health-related psychological quality of life, assessed using the 26-item World Health Organization Quality of Life-Brief (WHOQOL-BREF) (Harper et al., 1998). Secondary measures included three further dimensions of quality of life, also assessed by WHOQOL-BREF: physical health, social relationships, and environment. The Spanish validation of WHOQOL-BREF (Lucas Carrasco, 1998) has shown satisfactory internal consistency and adequate test-retest reliability (Mas-Expósito et al., 2011).

Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987) was included as a secondary measure to detect any changes in psychotic symptomatology. The PANSS is a semi-structured interview used for measuring symptom severity of patients with SMI. Each of the 30 items is scored from 1 to 7, higher scores reflecting greater psychopathology. For the purposes of this study, four PANSS scores were used: PANSS total, PANSS general psychopathology cluster, PANSS negative cluster, and PANSS positive cluster. Spanish adaptation is considered equivalent to original English form (Kay et al., 1990).

In order to detect changes in mindful awareness in everyday life the Mindfulness Attention Awareness Scale (MAAS) (Brown and Ryan, 2003) was used as secondary outcome. This 15-item scale focuses on attention/awareness component of mindfulness construct. The instrument can be independently used to assess individuals either with or without meditation experience and has been widely used in mindfulness research. The Spanish version of MAAS has good reliability indexes and good temporal stability (Soler et al., 2012).

2.4. Assessment

Patients were contacted by their regular psychiatrist to perform a personal interview. At interview each patient was informed about mindfulness and what participation in the trial would involve. At the end of the interview each patient, or his legal guardian, was invited to participate and to sign informed consent.

After informed consent for trial participation was signed, randomization identification was assigned to each patient and recorded in the clinical record form. A master randomization list was created to record randomization identifications and corresponding treatment assignment, access to master randomization list was restricted to psychologist and psychiatrist who led mindfulness sessions. Patients were randomly allocated by software to IRT or IRT+MBI group, with a group size for MBI of 10-12 (12 being the maximum size for groups with this client group). Each of two cohorts was randomised once numbers were sufficient to begin a mindfulness group. Once allocated, patients were assessed by a psychologist specifically trained to manage SMI patients and coordinate clinical trials who was blind to patient allocation. Psychological assessment consists in a videotaped PANSS interview followed by WHOQOL-BREF and MAAS questionnaires. PANSS interview was evaluated at the end of the study by two clinical psychologists from the local hospital service; both had no contact with patients and were blind to allocation. Access to master randomization list was restricted during the study to keep blinding.

2.5. Intervention

IRT consisted in pharmacotherapy combined with 26 one hour weekly sessions of cognitive behaviour therapy techniques for symptom management (e.g. sharing the cognitive ABC model, monitoring thoughts, feelings and behaviours), social skills training focussed on assertiveness, and psychoeducation about SMI management as well as strategies for preventing relapse and conflict management. IRT contained no mindfulness training or family intervention.

MBI groups ran throughout the 26 week rehabilitation treatment program (Carmody and Baer, 2009). Mindfulness group therapy sessions lasted 60 minutes and were carried out in venue ceded for free by city council. To help clients to ground every session began with a habituation

period to the room with relaxing music as background followed by 10-minute body awareness exercises led by a trained psychologist. Then, 15 minutes of guided meditation was led by a psychiatrist and a clinical psychologist trained in mindfulness and experienced in working with SMI patients. Frequent guidance was imparted in every mindfulness session encouraging awareness and acceptance of bodily sensations, sensations of breathing, and thoughts, images and voices that might arise. Guidance also encouraged participants to notice and let go of worry and engagement with the content of thoughts, voices or other psychotic symptoms that might arise, and of criticism or judgement. Finally, sessions included 15 minutes of reflective group discussion aimed at facilitating patients' understanding and insights drawn from the mindfulness practice. Guidance and reflection followed Chadwick et al. (2005, 2009). Home practice was encouraged between mindfulness sessions and participants were given an audio tape for home practice with the guidance instructions used during group sessions,

2.6. Statistical Analyses

Before proceeding to conduct any analysis over the outcomes variables, the assumption of multivariate normality and homogeneity of variances was tested. Both groups of participants were compared on baseline variables using Chi square and independent sample t tests.

As a manipulation check, analyses were conducted using repeated-measures analyses of variance (ANOVA) for different dependent variables (WHOQOL-BREF dimensions and MAAS) with Treatment condition (IRT, IRT+MBI) as between-participants factor and Time (baseline and post-treatment) as within-participants variable. In order to examine any significant difference in interaction between factors Bonferroni contrast was used. The level of statistical significance was set at 5%.

3. Results

Fifty one patients were assessed against inclusion criteria (Figure 1). Seven participants were excluded, 4 declined to participate and 3 did not meet inclusion criteria. Twenty two patients were allocated to IRT+MBI group and twenty two to IRT group. One patient did not complete IRT+MBI treatment, reporting that mindfulness intervention was not adequate for him, but continued in IRT alone. In IRT condition two patients did not complete intervention, one due to patient's decision of not to come back to IRT and one due to adverse events (hospitalization) who was not followed-up. Final statistical analyses included 44 participants. The sample was predominantly male (81.8%), with a mean age of 38.44 (SD=8.06), diagnosis of schizophrenia (89%), and mean duration of illness was 14.02 (7.01) years.

The first analyses checked the level of homogeneity between the mindfulness group and the waitlist group. Table 1 showed the results of these analyses. To check the assumption of normality, the Kolmogorov-Smirnov test was applied to: age ($Z(44)=0.82$, $p=0.51$), years since diagnosis ($Z(44)=1.33$, $p=.06$), positive PANSS ($Z(44)=.64$, $p=.8$), negative PANSS ($Z(44)=.71$, $p=.7$), General PANSS ($Z(44)=.6$, $p=.86$), and total PANSS ($Z(44)=.69$, $p=.73$). Levene tests were applied to these same factors to check homoscedasticity: age ($F(1,43)=1.88$, $p=.18$), years since diagnosis ($F(1,42)=05$, $p=.83$), positive PANSS ($F(1,42)=.34$, $p=.56$), negative PANSS ($F(1,42)=.13$, $p=.72$), General PANSS ($F(1,42)=1.81$, $p=.19$), and total PANSS ($F(1,42)=.02$, $p=.9$).-As is shown in Table 1, there is no difference between IRT and IRT+MBI groups in age, years since diagnosis, gender, education level or diagnosis.

The assumption of normality was checked using Kolmogorov-Smirnov test in WHOQOL-BREF and MAAS: physical health (QoL), Z(44)=.79, p=.55; psychological health (QoL), Z(44)=.77, p=.59; social relationships (QoL), Z(44)=.84, p=.49; environment (QoL), Z(44)=.83, p=.5; and MAAS, Z(44)=.56, p=.91.

A 2x2 ANOVA (Treatment x Time) for each measure was used. The WHOQOL-BREF results comparing IRT and IRT+MBI group in primary and secondary outcomes are summarized in Table 2. For every dimension, there are seven lines of results: the four simple effects, the two main effects -Treatment and Time-, and the interaction effect between these two factors. Our main hypothesis was based on the potential significance of this interaction.

On the primary outcome measure, psychological health-related quality of life, the interaction between Treatment and Time was clearly significant: F (1, 42) = 16.72; p<.001; η^2=.285. The analysis of simple effects of this interaction showed that there were significant differences between the Pre and Post assessments in the IRT+MBI group -F(1,42)=25.49; p<.001; η^2=.378, but not in the IRT group -F(1,42)=.54; p=.467, η^2=.013. On the other hand, there were significant differences between the two groups in the Post assessment -F (1, 42) =5.44; p=.025, η^2=.115, but not in the Pre assessment -F (1, 42) =.36; p=.55, η^2=.009.

Secondary measures of physical and environmental health showed significant differences in the WHOQOL-BREF. Significant differences were found in Time factor on physical health (F (1, 42) =7.23; p=.01; η^2=.147), simple effects analysis showed significant differences between Pre and Post in IRT+MBI group (F (1, 42) =6.69; p=.013; η^2=.137). Time factor was found significant in environment dimension (F (1, 42) =11.21; p=.002, η^2=.211) and simple effects analysis showed statistical differences between Pre and Post in IRT+MBI group: F (1, 42) =11.21; p=.002; η^2=.21. There were no effects on social quality of life.

The same ANOVA 2x2 (Treatment x Time) was applied to PANSS and MAAS data. There were no significant differences in PANSS Positive scores. For PANSS Negative scores, there was a significant Treatment-Time interaction -F (1, 42) =4.44; p=.041, η^2=.096-, and simple effects analysis showed a statistical trend between Pre and Post assessments in IRT+MBI (p=.063, η^2=.08). PANSS General scores showed significant differences in Time factor -F(1,42)=5.54; p=.023, η^2=.117-, when simple effects were analysed statistical differences were found in IRT+MBI (F(1,42)=4.6; p=.038, η^2=.099) group, but not in IRT group (F(1,42)=1.4; p=.243, η^2=.032). For MAAS there were no differences in the interaction or the main effects (Table 2).

4. Discussion

The main finding of our study indicates that adding a mindfulness-based intervention (MBI) to an integrated rehabilitation treatment (IRT) yielded improved psychological health-related quality of life (QoL) in people with severe mental illness, 89% of whom had a diagnosis of schizophrenia. Psychological QoL, as defined by the WHO, comprises self-esteem, positive feelings and bodily image, and reduced frequency of negative feelings (Harper et al., 1998). Data suggests that mindfulness intervention accounts for 38% of variance in health-related psychological QoL. Secondary measures indicated broader QoL benefits of the combination of MBI+IRT, with significant improvement in scores for physical and environmental dimensions.

Study retention rate was high (93%), with only one drop-out from MBI+IRT, and two from IRT, and there were no adverse events in the MBI participants.

Our results are convergent with previous findings about MBI in psychosis (Chadwick et al., 2009; Gaudiano et al., 2010; Langer et al., 2012), and go further assessing its effectiveness and feasibility as an add-on to IRT in a public community rehabilitation centre. The improvement on psychological health-related QoL in people with SMI may be due in part to change in the relationship with their symptoms – a finding reported in a qualitative study of mindfulness for psychosis (Abba et al., 2008). According to Hayes, the more a person resists symptoms, the more likely functional impairment will result, as individuals forgo the pursuit of their goals due to avoidance of internal distress (Hayes et al., 1999). Mindfulness supports "cognitive defusion", a metacognitive process aimed at undermining the literal quality of thoughts so that they are experienced more specifically as thoughts (I'm having the thought "I am going crazy") rather than as their literal content ("I am going crazy") (Gaudiano and Herbert, 2006). As patients learn to let go of struggle and reactivity, psychotic experiences come to be accepted as transient experiences that do not define the self and patients report reclaiming power from psychotic symptoms (Abba et al., 2008).

The frequency and intensity of positive psychotic symptoms did not change due to mindfulness intervention. This finding is congruent with previous studies on people with a diagnosis of schizophrenia (Chadwick et al., 2009; Langer et al., 2012), and indeed it has been argued that reduction in positive symptoms is not a target in mindfulness-based interventions (Bach & Hayes, 2002). There is, however, emerging evidence that MBIs affect negative symptoms, with a recent meta-analysis reporting small to medium effect sizes (Khoury et al., 2013). The present study found a statistical trend towards improvement in PANSS negative symptoms in IRT+MBI treatment; this exploratory finding is consistent with Khoury et al's conclusion that mindfulness affects this symptom cluster. Additionally, PANSS data suggest that mindfulness intervention may also reduce general psychopathology of this client group. Further research on outcomes, mediators and moderators, is needed.

There were no statistically significant differences in mindfulness scores, despite the effect size registered. This may reflect the small sample size, or the decision to use a measure of mindfulness in everyday life rather than a measure that targets mindfulness of difficult cognitions, such as the Southampton Mindfulness Questionnaire (Chadwick et al., 2008) which showed effects in earlier research on mindfulness for psychosis. Choice of outcomes and assessment tools in psychological therapies for psychosis remains an ongoing challenge.

The study has limitations that deserve mention. The sample size is small (though sufficient to test the primary outcome), with an uneven gender distribution of the sample, as 81% were male – though this gender imbalance is in line with the prevalence of SMI in the general population (NIMH, 2013). Also, in keeping with the initial aims of a pilot research clinical trial, the study aimed at exploring only immediate benefits of adding mindfulness to integrated rehabilitation care; future research could explore maintenance of gains. The main strengths are the randomized design with blind assessment; the first data on psychological quality of life following mindfulness in this client group; and the use of a well-defined active control treatment (because participants were drawn from the same community public healthcare service, integrated rehabilitation care was consistent across all participants and comprised medication, cognitive-behaviour therapy, and education towards illness management).

The findings of our study are encouraging and warrant a full trial. Future research should include a follow-up phase and assess impact on service use (e.g. drug prescription), relapse and rehospitalisation. Further research should also collect qualitative data to extend understanding of underlying processes triggered by mindfulness training (e.g. Abba et al., 2008). Nevertheless results showed that the inclusion of mindfulness within rehabilitation has potential to enhance quality of life, and perhaps even reduce negative symptoms. In summary, the study lends further support to the view that when adapted for people with SMI, mindfulness-based group interventions are acceptable, safe and therapeutic, and supports the call (Chadwick, 2014) for careful practice and research into the efficacy and effectiveness of mindfulness based interventions for people with psychosis and other severe mental health problems.

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Table 1: Clinical and demographic characteristics

	Total Sample (n=44)	IRT Group (n= 22)	IRT+MBI Group (n=22)	Statistics
Age (mean, SD)	38.84 (8.06)	38.77 (8.93)	38.73 (7.46)	t= 0.018 p= 0.985
Sex (n, %)				
1. Man	36 (81.8)	17 (77.3)	19 (86.4)	χ^2= .611 p= .698
2. Woman	8 (17.2)	5 (22.7)	3 (13.6)	
Years since diagnosis (mean, SD)	14.02 (7.01)	14.05 (7.44)	14 (6.79)	t= 0.024 p= 0.981
Diagnosis (n, %)				
1. Paranoid Schizophrenia	20 (45.4)	10 (45.5)	10 (45.5)	χ^2= 1.111 p= 0.953
2. Schizoaffective disorder	9 (20.4)	4 (18.2)	5 (22.7)	
3. Undifferentiated schizophrenia	6 (13.6)	4 (18.2)	2 (9.1)	
4. Disorganized Schizophrenia	4 (9.1)	2 (9.1)	2 (9.1)	
5. Bipolar disorder	3 (6.8)	1 (4..5)	2 (9.1)	
6. Delusional disorder	2 (4.7)	1 (4.5)	1 (4.5)	
Age left education (n, %)				
1. 14 years old or less	20 (45.4)	11 (50)	9 (40.9)	χ^2= 0.368 p= 0.832
2. Between 15 and 17 years old	13 (29.5)	6 (27.3)	7 (31.8)	
3. 18 years old or more	11 (25.1)	5 (22.7)	6 (27.3)	

Table 2: ANOVA Analysis.

SCALE mean (SD)		PRE	POST	F	p value	η^2
Physical QoL	IRT	21.5 (3.03)	22.23 (3.01)	1.48	.230	.034
	IRT+MBI	21.18 (3.3)	22.73 (3.41)	**6.69**	**.013**	**.137**
	PRE			.11	.741	.003
	POST			.27	.609	.006
	Treatment			0.01	.917	<.001
	Time			**7.23**	**.010**	**.147**
	Treatment x Time Interaction			.94	.338	.022
Psychological QoL	IRT	18.45 (4.17)	18.09 (4.17)	.54	.467	.013
	IRT+MBI	17.78 (3.28)	20.27 (2.64)	**25.49**	**<.001**	**.378**
	PRE			.36	.55	.009
	POST			**5.44**	**.025**	**.115**
	Treatment			.59	.447	.014
	Time			**9.31**	**.004**	**.181**
	Treatment x Time Interaction			**16.72**	**<.001**	**.285**
Social Relationship QoL	IRT	7.91 (2.22)	8.5 (1.76)	1.48	.231	.034
	IRT+MBI	7.95 (2.19)	8.1 (2.67)	.09	.763	.002
	PRE			.01	.946	<.001
	POST			.28	.597	.007
	Treatment			.07	.79	.002
	Time			1.15	.289	.027
	Treatment x Time Interaction			.42	.523	.010
Environment QoL	IRT	23.95 (3.86)	25.09 (3.46)	1.94	.171	.044
	IRT+MBI	24.23 (4.51)	26.95 (3.95)	**11.18**	**.002**	**.21**
	PRE			.05	.831	.001
	POST			2.76	.104	.062
	Treatment			1.04	.314	.024
	Time			**11.21**	**.002**	**.211**
	Treatment x Time Interaction			1.9	.175	.043
MAAS	IRT	45.09 (14.22)	43.04 (12.51)	.61	.438	.014
	IRT+MBI	43..09 (14.39)	45.81 (14.33)	1.09	.303	.025
	PRE			.21	.645	.005
	POST			.47	.498	.011
	Treatment			.01	.919	<.001
	Time			.03	.855	.001
	Treatment x Time Interaction			1.67	.204	.038
PANSS Positive	IRT	15.95 (6.22)	15.41 (6.99)	.43	.516	.01
	IRT+MBI	17.95 (6.58)	16.82 (6.24)	1.86	.179	.042
	PRE			1.07	.306	.025
	POST			.5	.484	.012
	Treatment			.83	.368	.019
	Time			2.04	.16	.046
	Treatment x Time Interaction			.25	.618	.006
PANSS Negative	IRT	20.04 (6.23)	21.09 (5.91)	1.15	.29	.027
	IRT+MBI	21.72 (6.33)	19.86 (6.2)	3.65	.063	.080
	PRE			.79	.38	.018
	POST			.45	.505	.011
	Treatment			.02	.896	<.001
	Time			.56	.556	.008

	Treatment x Time Interaction			**4.44**	**.041**	**.096**
PANSS General	IRT	40.14 (11.06)	38.45 (11.59)	1.4	.243	.032
	IRT+MBI	41.45 (7.22)	38.41 (6.62)	**4.6**	**.038**	**.099**
	PRE			.22	.642	.005
	POST			.01	987	<.001
	Treatment			.06	.811	.001
	Time			**5.54**	**.023**	**.117**
	Treatment x Time Interaction			.46	.501	.011

IRT and IRT+MBI rows reflect interaction analysis for Time factor (Within subjects)
PRE and POST rows reflect interaction analysis for Treatment factor (Between subjects)

Figure 1. CONSORT flowchart